IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF NEW YORK

THE COUNTY OF ALBANY, NEW YORK,	Civil Action No.: 1:19-cv-273 (DNH	/CFH

Plaintiff,

v.

CARDINAL HEALTH, INC.; KINRAY, LLC; MCKESSON CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; WALGREENS BOOTS ALLIANCE D/B/A WALGREEN CO.; H.D. SMITH WHOLESALE DRUG CO.; ROCHESTER DRUG CO-OPERATIVE, INC.; CVS HEALTH CORPORATION; RITE AID CORPORATION; RITE AID OF MARYLAND, INC. D/B/A RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC.; AND JANE DOES 1-50,

Defendants.	

COMPLAINT

Jury Trial Requested

The Plaintiff, by and through its attorneys, Motley Rice LLC, submits its Complaint herein and alleges the following:

PRELIMINARY STATEMENT

1. Plaintiff, the County of Albany, New York (the "County"), brings this action to prevent future harm and to redress past wrongs, to remedy AmerisourceBergen Drug Corporation's, Cardinal Health, Inc.'s, Kinray, LLC's, McKesson Corporation's, Walgreens Boots Alliance d/b/a Walgreen Co.'s, H.D. Smith Wholesale Drug Co.'s, Rochester Drug Cooperative, Inc.'s, CVS Health Corporation's, Rite Aid Corporation's, and Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc.'s (hereinafter collectively referred to as "Defendants") unfettered and unlawful distribution of opioids into the County.

- 2. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care. Consequently, the prescribing of opioids was sharply constrained.
- 3. In the mid-1990s, however, pharmaceutical companies (which the County is suing in a separate action) aggressively and deceptively marketed opioids for common chronic conditions like back pain, migraines, and arthritis. By the mid-2000s, chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—became widespread and the use of opioids skyrocketed. According to the Centers for Disease Control and Prevention ("CDC"), opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S.
- 4. Taking advantage of this mass market, and conspiring with the major manufacturers to maintain it, Defendants flooded many communities with opioids, without conducting the due diligence required by law to prevent the diversion of opioids to an illicit market for these drugs that predictably developed, and that Defendants helped to create, expand, and maintain.

¹ In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

- 5. Nationally, Defendants AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation account for approximately 90% of all revenues from prescription drug distribution in the U.S. Known colloquially as the "Big Three," these Defendants dominate the wholesale drug distribution market, including, upon information and belief, in the County. The other defendants are also significant wholesale distributors of prescription opioids whose opioids, upon information and belief, are distributed in significant volumes in New York.
- 6. Wholesalers are paid to securely deliver opioids made by the various manufacturers and are the closest link to pharmacies throughout the country. As registered distributors and/or dispensers of controlled substances, Defendants are placed in a position of special trust and responsibility. From these positions, the Defendants had unique information and insight into likely diversion of the drugs they supplied and/or dispensed.
- 7. Defendants have common law and statutory duties to provide adequate controls against diversion. Each Defendant is legally mandated to monitor for, report, and reject suspicious orders of controlled substances into the County. Such orders include, for example, orders of opioids that exceed reasonable volume, are of an unusual frequency, or that raise other red flags. Yet, Defendants shipped orders that they knew or should have known were being diverted or used other than for legitimate medical purposes.
- 8. Sales and distribution data available to Defendants, as well as their own observations, would, or should, have put them on notice of potential diversion. Yet, upon information and belief, Defendants consistently failed to report or suspend these illicit orders, deepening the crisis of opioid abuse, addiction, and death in the County. Defendants had financial incentives to continue to supply opioids to pill mills (doctors, clinics, or pharmacies

that prescribe or dispense opioids inappropriately or for non-medical reasons) because they may entitle them to volume-based rebates and discounts that they may then leverage to further increase their sales volumes and profits. Defendants have supplied opioids in quantities that they knew or should have known exceeded any legitimate market for opioids—even the wider market for chronic pain—and, upon information and belief, ignored red flags of suspicious orders of these drugs in Albany County.

- 9. As a direct and foreseeable result of Defendants' conduct, the nation and Albany County are now swept up in what the CDC has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis." In 2015, an estimated 2 million Americans were addicted to prescription opioids and 591,000 to heroin. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. In 2016, the CDC reported that, in contrast to other developed countries, and despite having some of the world's highest spending on medical care, our nation saw life expectancy at birth decline for the second straight year, with the increasing number of people who died of overdoses representing the most significant factor in this alarming trend.
- 10. The outcomes in New York, including Albany County, are equally catastrophic—and getting worse. Total drug deaths in Albany County increased by 29% from 2010 to 2015. In 2016, the County saw 11 heroin deaths and 8 deaths involving opioid pain relievers, 113 outpatient visits and 23 hospitalizations for opioid overdoses, and 1,194 unique clients admitted

² CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org.

to treatment programs for heroin and other opioids. Albany County had 31 opioid overdose deaths in 2015, ranking higher than 46 of New York's 62 counties.

- 11. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market. Rather than maintaining effective controls over the distribution of prescription opioids, Defendants instead have actively sought to evade such controls.
- 12. The careless, even reckless distribution of opioids into the County correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids. Prescription opioids at the molecular level and in their effect, closely resemble heroin. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.
- 13. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. And, the link between prescription narcotic painkiller abuse and subsequent and/or simultaneous heroin abuse continues to grow. Across the country, 80% of recent heroin users have previously used prescription opioids non-medically. As the American Society of Addiction Medicine has explained, four out of five new heroin users started with prescription painkillers. In fact, people who are addicted to prescription opioids are 40 times more likely to become addicted to heroin, and the Centers for Disease

Control and Prevention ("CDC") identified addiction to prescription opioids as the strongest risk factor for heroin addiction.

- 14. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into New York communities.
- 15. Not only has the opioid epidemic been described as the deadliest drug crisis in American history, drug overdoses rose to become the leading cause of death for Americans under 50 years old, eclipsing guns or car accidents. Overdoses have been killing people at a pace faster than the H.I.V. epidemic did at its peak. According to Robert Anderson, who oversees death statistics at the CDC, "I don't think we've ever seen anything like this. Certainly not in modern times."
- 16. Albany County is no exception to this deadly trend. Across New York, the data has revealed a deepening crisis. The number of people who have died of opioid related overdoses in the State has surged dramatically, and Naloxone, the antidote to overdose, has been administered during 12,000 emergency calls in the State in a single year. One in four people in the Capital Region know someone who has died of an opioid overdose. According to a 2018 survey, across the state, one in two New Yorkers has been impacted by the epidemic, and the lives of 58% percent of people in the Capital Region have been touched by the opioid crisis.
- 17. Defendants' scheme has violated, and continues to violate, New York General Business Law §§ 349's & 350's prohibitions on unfair or deceptive acts and practices and false

³ Associated Press, *Drug Overdoses Killed 50,000 in U.S., More than Car Crashes*, (Dec. 9, 2016), https://www.nbcnews.com/health/health-news/drug-overdoses-killed-50-000-u-s-more-car-crashes-n694001

advertising, and further violates New York Social Services Law § 145-B. Additionally, Defendants are liable for creating and maintaining a public nuisance, negligence, fraud, and unjust enrichment.

18. Accordingly, the County brings this action to hold Defendants accountable for their conduct and seeks abatement, damages, and any other injunctive and equitable relief within this Court's powers to redress and halt these unlawful practices.

THE PARTIES

A. The Plaintiff

19. Albany County includes a total of 19 villages, towns, and cities within New York. The County provides many services for its residents, including public health, public assistance, and law enforcement services, emergency care, and services for families and children, including through 82 separate behavioral health programs across 26 community agencies.

B. <u>The Defendants</u>

- 20. Defendant Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the United States, with annual revenue of \$121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to U.S. patients travels through the Cardinal Health network.
- 21. Defendant Kinray, LLC ("Kinray") is a full-service pharmaceutical wholesaler for independent pharmacies. Kinray is a New York corporation with its principal place of business in Whitestone New York. Kinray is a subsidiary of Cardinal.

- 22. Defendant McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of \$191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in Delaware and its principal place of business is in San Francisco, California. One of McKesson's distribution centers is located in Rochester, New York.
- 23. In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids, and for failing to maintain effective controls against diversion at McKesson distribution centers.
- 24. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country.

 AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania and it is incorporated in Delaware. On January 3, 2018, AmerisourceBergen announced that it had completed the acquisition of wholesaler H.D. Smith.
- 25. Defendant H.D. Smith Wholesale Drug Company ("H.D. Smith") is a privately held independent distributor of wholesale brand, generic, and specialty pharmaceuticals. H.D. Smith is a Delaware corporation with its principal place of business in Springfield, Illinois.
- 26. Defendant Rochester Drug Co-operative, Inc. ("Rochester Drug") is a regional wholesale drug cooperative owned and directed by independent pharmacies. It distributes pharmaceuticals to ten states in the northeast and is ranked as the seventh largest distributor in the United States. Rochester Drug is a New York Corporation with its principal place of business in Rochester, New York.

- 27. Defendant CVS Health Corporation ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. Based on Defendant's own estimates, CVS Pharmacy stores dispense more prescriptions than any other drugstore chain.
- 28. Defendant Rite Aid Corporation is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid, through its various DEA registrant subsidiaries and affiliated entities, distributed prescription opioids throughout the United States. Defendant Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. distributed prescription opioids throughout the United States. Defendants Rite Aid Corporation and Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. are collectively referred to as "Rite Aid."
- 29. In 2006, Rite Aid Corp. purchased the U.S. Eckerd and Brooks operations of Canada's Jean Coutu Group Inc. Rite Aid described the deal as making it the largest drugstore chain operator on the East Coast and giving the company a larger presence in major cities such as Atlanta, Philadelphia, New York, and Baltimore. The purchase included more than 1,850 drugstores and six distribution centers, located across 18 states, primarily on the East Coast. The distribution centers included facilities in Syracuse, NY and Bohemia, NY, as well as in Atlanta, GA; Charlotte, NC; Philadelphia, PA; and Dayville, CT.
- 30. Walgreens Boots Alliance d/b/a Walgreen Co. ("Walgreens") is a Delaware corporation with its headquarters in Deerfield, Illinois. Walgreens for years included a captive distributor that supplied pharmaceutical drugs and opioids to Walgreens pharmacies in Albany

County and throughout the country. Walgreens also operates pharmacy locations dispensing prescriptions, including opioids, in the County. Nationwide, Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than \$,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal year 2017.

- 31. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the distribution, sale and/or dispensing of opioids.
- 32. For Defendant Jane Does 1-50, the County lacks sufficient information to specifically identify the true names or capacities, whether individual, corporate, or otherwise, of these Defendants. The County will amend this Complaint to show their true names when they are ascertained.
- 33. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

JURISDICTION AND VENUE

34. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because the County's claim under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.* raises a federal question. This Court has supplemental jurisdiction over the County's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

- 35. This court has personal jurisdiction over Defendants Kinray and Rochester Drug because they are New York corporations, and over all Defendants under New York Civil Practice Law and Rules 302 because they, in person or through agents, transact business in this state and contract to supply goods in this state, have committed and are committing tortious acts in this state causing injury to people and property in this state, regularly do or solicit business, or engage in a persistent course of conduct, or derive substantial revenue from goods used or consumed or services rendered in this state, or expect or should reasonably expect their conduct to have consequences in New York and derive substantial revenue from interstate commerce.
- 36. Venue as to each Defendant is proper in this court under 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the Northern District of New York. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants reside, are found, have agents, or transact their affairs in this district.
 - A. <u>Defendants Deliberately Disregarded Their Duties to Report and Terminate Suspicious Orders.</u>
 - 1. <u>Defendants have a duty to report suspicious orders and not to ship those orders unless due diligence disproves their suspicions.</u>
- 37. By the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. This created both a vastly and dangerously larger market for opioids in Albany County and a lucrative opportunity for Defendants, who compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

- 38. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.
- 39. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding the County with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached their duty to exercise reasonable care in delivering narcotic substances and both created and failed to prevent a foreseeable risk of harm to the County.
- 40. Second, each Defendant assumed a duty, when speaking publically about opioids and its efforts and commitment regarding diversion of prescription opioids, to speak accurately and truthfully.
- 41. Third, Defendants violated their statutory obligations under the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* and under New York law, which also incorporates the federal CSA" and its implementing regulations. Each of the Defendants was required to register with the DEA to distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. As registrants, Defendants were required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. Defendants were further required to take steps to halt suspicious orders.
- 42. Fourth, under New York law, distributors of a controlled substance must be licensed by the New York Department of Health. *See* N.Y. Pub. Health Law § 3310. New York's Public Health Law requires that registration, or licensure, be consistent with the public interest, and specifically requires that the applicant "will be able to maintain effective control"

against diversion of controlled substances" and "will be able to comply with all applicable state and federal laws." N.Y. Pub. Health Law § 3313. *Accord* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100 (DEA registration requirements).

- 43. New York law further provides that "[a]ny person licensed under this title or operating a registered outsourcing facility shall forthwith notify the department of any incident involving the theft, loss or possible diversion of controlled substances manufactured, compounded, delivered or distributed by the licensee or operator." N.Y. Pub. Health Law § 3322.
- 44. Furthermore, New York regulations mandate that a licensee "shall establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department [of health of the state of New York] of such suspicious orders." N.Y. Comp. Codes R. & Regs. tit. 10 § 80.2210 (NYCRR 80.22). These regulations define suspicious orders as including, but not limited to, orders of unusual in size *or* frequency *or* deviating substantially from a normal pattern. *Id*.
- 45. Federal regulations issued under the CSA and incorporated into New York law pursuant to Public Health Law § 3310 *et seq.* likewise require that distributors satisfy registration requirements and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, ordering the same controlled substance from multiple distributors.

- 46. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.
- Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert distributors to potential problems. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply—can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual given the customer's history or its comparison to other customers in the area.
- 48. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants and licensees in the distribution chain of controlled substances, have several responsibilities with respect to suspicious orders of opioids. First, they must set up

a system designed to detect such orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All flagged orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.⁴

- 49. These statutes and regulations reflect a standard of conduct and care below which reasonably prudent distributors would not fall. Together, these laws and industry guidelines make clear that wholesalers of controlled substances possess, and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.
- 50. Further, these laws and industry guidelines make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

2. <u>Defendants understood the importance of their reporting and due diligence obligations.</u>

51. The reason for the reporting rules is to create a "closed" system intended to reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the

⁴ See Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of New York); Masters Pharmaceutical, Inc. v. Drug Enforcement Administration, 861 F.3d 206 (D.C. Cir. 2017) (same).

same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.⁵ In enacting the CSA in 1970, the U.S. Congress recognized a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety. The CSA and its implementing regulations created a closed system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.

- 52. "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).
- 53. Both because wholesale distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a

⁵ See 1970 U.S.C.C.A.N. 4566, 4571-72.

distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.⁶

54. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences. In fact, trade organizations to which Defendants belong have acknowledged that wholesale distributors such as Defendants have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which Defendants AmerisourceBergen, Cardinal, and McKesson, belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society." Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to

 $^{^6}$ See Rannazzisi Decl. ¶ 10, filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

⁷ See Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *4 (D.C. Cir. Apr. 4, 2016) (stating that regulations "in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA . . .") (emphasis omitted).

⁸ See Amicus Curiae Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

perform due diligence in order to help support the security of the controlled substances they deliver to their customers."

- 55. The FTC, too, has recognized the unique role of wholesale distributors. Since their inception, Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, these Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with generic manufacturers and offer services that include software assistance and other database management support. See Fed. Trade Comm'n v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.
- 56. As national pharmacy chains, or affiliates of such chains, CVS, Walgreens, and Rite Aid have especially deep knowledge of their retail stores' orders, prescriptions, and

⁹ Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

customers. This is underscored by the fact that Walgreens is able to sell the contents of its patients' prescriptions to data-mining companies such as IMS Health, Inc. In 2010, for example, Walgreens' fiscal year 2010 SEC Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at \$749,000,000.

- 57. The DEA also repeatedly has made clear that Defendants' obligations under federal law, mirrored in and incorporated by New York law, *see infra* ¶¶ 41-44, obligate them to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.
- 58. The DEA also, for example, advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances (which included Defendants) that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." The DEA's September 27, 2006 letter also

¹⁰ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in

expressly reminded them that registrants, *in addition* to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."

- 59. The DEA sent another letter to distributors and manufacturers alike on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious." 13
 - 3. <u>Despite repeated admonitions, Defendants have repeatedly violated their reporting and due diligence obligations.</u>
 - a. Cardinal, McKesson, and AmerisourceBergen

Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (hereinafter "2006 Rannazzisi Letter") ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

¹¹ *Id*.

¹² Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health*, *Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (hereinafter "2007 Rannazzisi Letter").

¹³ *Id*.

- 60. Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.
- 61. Governmental agencies and regulators have confirmed (and in some cases

 Defendants have admitted) that Defendants did not meet their obligations, and have uncovered especially blatant wrongdoing.
- 62. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. These included a number of actions against AmerisourceBergen, Cardinal, and McKesson:
- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");
- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.
- 63. In its 2016 Settlement Agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:
 - a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b);"
 - b. "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5);" and
 - c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."
- 64. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of

Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."¹⁴ Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."15 McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers." Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from a number of McKesson facilities. 16

¹⁴ Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) (hereinafter "2017 Settlement Agreement and Release" or the "2017 Agreement") ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

¹⁵ *Id*.

¹⁶ Other facilities included McKesson's distribution centers in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; and West Sacramento, CA.

- 65. As the *Washington Post* and 60 *Minutes* have reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against the 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion." Investigators found certain warehouses "were supplying pharmacies that sold to criminal drug rings."
- 66. Even the far lessor-than recommended civil penalty against McKesson, a \$150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four different states. Though this penalty too, was far less severe than investigators had recommended, as the DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."²⁰
- 67. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information

¹⁷ Lenny Bernstein and Scott Higham, "We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper, Washington Post (Dec. 17, 2017).

¹⁸ *Id*.

¹⁹ *Id*.

²⁰ Department of Justice, "McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

- a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review;"
- b. "[d]ocumentation evidencing new customer due diligence was incomplete;"
- c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete;" and
- d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."
- 68. Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally.
- 69. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted.²¹ Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements

²¹ Lenny Bernstein and Scott Higham, "'We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper, Washington Post (Dec. 17, 2017), https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-

<u>62589434a581_story.html?utm_term=.d6e92f349f47</u>

²² *Id.* (quoting a March 30, 2015 DEA memo).

of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings." "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."

70. Further, in a *60 Minutes* interview in the fall of 2017, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die."²⁵ He further explained that:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. Thats exactly what they did. ²⁶

71. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100

²³ *Id*.

²⁴ *Id*.

²⁵ Bill Whitaker, *Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and* Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress

 $^{^{26}}$ *Id*.

²⁷ *Id*.

percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."²⁸

- 72. At a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, the chief executives of McKesson and Cardinal, among others, testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. He also testified that Miami-Luken had severed relationships with many customers that continue to do business with other distributors. Despite the frequent prior enforcement actions described above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. In fact, both executives' answers confirmed gaps and breakdowns in past and current practices.
- 73. For example, Cardinal's former Executive Chairman, George Barrett, denied that "volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious *orders*, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Despite a Cardinal employee flagging an especially prolific pharmacy as a potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in response. In addition, Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

28	Id.
----	-----

74. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of a single page. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c) examined and documented every order over that threshold, the company still shipped 36 times the monthly threshold to one pharmacy—9,500 pills *per day*.

b. Walgreens

- 75. Walgreens also has been penalized for serious and flagrant violations of the CSA. On February 12, 2012, the DEA issued an Order to Show Cause and Immediate Suspension of Registration against Defendant Walgreens' Jupiter, Florida distribution center, ("Jupiter Center") for failure to maintain effective controls against the diversion of opioids. The DEA found, among other things, that the Jupiter Center failed to conduct adequate due diligence and should have known that the Walgreens pharmacies were dispensing controlled substances, including opioids, for other than legitimate medical purposes.
- 76. In June 2013, Walgreens agreed to the largest settlement in DEA history at the time—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA at the Jupiter Center and six Walgreens retail pharmacies in Florida, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales. The Department of Justice, in describing the settlement, explained that the conduct at issue included Walgreens' "alleged failure to sufficiently report suspicious orders was a systematic practice that

resulted in at least tens of thousands of violations and allowed Walgreens' retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone."²⁹

- 77. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount. In addition to the monetary payment, the Jupiter, Florida distribution center lost its authority to distribute or dispense controlled substances, including opioids, for two years. This revocation ended in 2014.
- 78. The Jupiter Center supplied prescription opioids to two Walgreens pharmacies in Oviedo, Florida, one of which increased its oxycodone prescriptions from 6,600 dosage units in June 2010 to 169,780 dosage units in June 2011. Multiple arrests at the Oviedo Walgreens for illicit sales prompted the local chief of police to write letters to the Chairman and CEO of Walgreens and asked for their assistance in fighting the prescription drug epidemic. In the letter, the police chief reported that at both locations drugs were "sold, distributed as payment, crushed, and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies."³⁰
- 79. Walgreens' Jupiter Center continued to supply prescription opioids to the Oviedo pharmacies, and increased its quantities of 30 mg oxycodone from 73,300 tablets in February

²⁹ Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

³⁰ In the Matter of Walgreens Co. *Order to Show Cause*, September 13, 2012.

2011, to 145,300 dosage units in July 2011. The Jupiter Center nearly doubled its distribution of oxycodone to one of these pharmacies within a six month period.

- 80. The Jupiter Center, along with Defendant Walgreens' headquarters, ignored warnings and concerns from its own employees about large shipments of opioids. In January 2011, the Center's Function Manager, who was responsible for all Schedule II drug operations (including opioids), sent an email to the manager of Walgreens' drug stores at its headquarters about the suspiciously "large quantity," of oxycodone that was being ordered by three stores in Florida. The Jupiter Center continued to supply opioids to these locations, and provided a Walgreens' pharmacy in a town of less than 3,000 people with 285,800 30 milligram doses of oxycodone in January 2011. Despite the warning from an employee, Defendant Walgreens did not report any of these orders as suspicious.
- 81. Instead, Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," ³² underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.
- 82. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in

 $^{^{31}}$ *Id*.

 $^{^{32}}$ *Id*.

June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

83. Walgreens' misconduct was not limited to Florida. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.

c. Kinray

84. In 2016, the United States Attorney for the Southern District of New York settled a civil lawsuit on behalf of the United States with Kinray for violations of the CSA. Kinray admitted that it had failed to report suspicious orders for oxycodone or hydrocodone to the DEA. From January 1, 2011 to May 14, 2012, Kinray had shipped these drugs to more than 20 New York-area pharmacy locations in much greater quantities than Kinray's average sales of controlled substances to all of its customers. Yet, Kinray did not report any suspicious orders to the DEA for most of this time period. Kinray settled the lawsuit for \$10 million.

d. H.D. Smith

85. H.D. Smith has also been found to have violated, routinely, its duties to report suspicious orders and halt suspicious shipments of prescription opioids. According to a recent letter from the U.S. House of Representatives Committee on Energy and Commerce, data provided to the Committee showed that between 2007 and 2008, H.D. Smith provided two pharmacies in Williamson, WV, a town with a population of 3,191, combined total of nearly 5 million hydrocodone and oxycodone pills - approximately 1,565 hydrocodone and oxycodone pills for every man, woman, and child in Williamson, WV. According to press reports, H.D.

Smith distributed approximately 13.7 million hydrocodone and 4.4 million oxycodone pills to West Virginia between 2007 and 2012. Press accounts further indicate that H.D. Smith did not submit any suspicious order reports to the state for at least a decade.

e. Rite Aid

86. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA. The investigation revealed that from 2004 onwards, Rite Aid had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated, including in New York. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

f. CVS

- \$40 million as the result of a series of investigations by the DEA and the United States

 Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.
- 88. As recently as June 2018, CVS Pharmacy, Inc. agreed to pay \$1.5 to settle civil penalty claims stemming from a DEA investigation of CVS pharmacy stores in Nassau and Suffolk Counties on Long Island. The DEA's investigation revealed that these pharmacies failed to timely report the loss or theft of controlled substances, including hydrocodone, one of the most commonly diverted controlled substances.

- 89. This fine was preceded by numerous others throughout the country.
- 90. Just last year, in July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.
- 91. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.
- 92. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.
- 93. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.
- 94. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.
- 95. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally

permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

- 96. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."³³
- 97. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.
- 98. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.
- 99. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

g. Rochester Drug

100. On July 9, 2015, Preet Bharara, the former United States Attorney for the Southern District of New York, James J. Hunt, the Special Agent-in-Charge of the New York

³³ Department of Justice, U.S. Attorney's Office, Middle District of Florida, Press Release, *United States Reaches \$22 Million Settlement Agreement With CVS for Unlawful Distribution of Controlled Substances* (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution

Field Division of the U.S. DEA, and William J. Bratton, the former Commissioner of the New York City Police Department ("NYPD"), announced that the United States filed and settled a civil lawsuit against Rochester Drug.

- pharmacies in the New York City area, the DEA discovered that the pharmacies had reported thousands of purchase orders from Rochester Drug that Rochester Drug did not correspondingly report to the DEA through ARCOS. In response, in 2013, the DEA's New York Field Division Tactical Diversion Squad conducted an on-site investigation and audit at Rochester Drug's headquarters in Rochester, New York. The DEA's audit confirmed that Rochester Drug's ARCOS reporting system was underreporting many thousands of drug sales to pharmacies throughout the northeast region.
- 102. Rochester Drug responded that it expected to be able to resolve this issue through the pending acquisition of a new computer ordering system. But in 2014, DEA re-assessed Rochester Drug's compliance, and discovered that Rochester Drug had not implemented the new order system. As a result, Rochester Drug's failure to electronically report thousands of shipments of CSA-controlled substances, including Oxycodone and its variants, continued. During this time, the DEA also determined that Rochester Drug had failed to report the theft or significant loss of controlled substances in ARCOS, as required by the CSA and its implementing regulations.
- 103. In the settlement agreement, Rochester Drug admitted that between July 2013 and July 2014, it failed to report any electronic distribution transactions in its DEA ARCOS reports, and admitted that between July 2012 and July 2014, it failed to provide the required theft or significant loss reporting in ARCOS to the DEA. Under the Consent Order, Rochester Drug paid

\$360,000 in civil penalties to the United States and agreed to reconstruct complete and correct historical ARCOS data for the last five years for submission to the DEA.

- 104. More recently, a lawsuit by the company's former Chief Executive Officer ("CEO"), Laurence F. Doud, against Rochester Drug and its current CEO, Joseph Brennen, alleged that Rochester Drug has been under the cloud of a criminal investigation for more than a year. Mr. Doud alleged that on March 8, 2017, the Department of Justice ("DOJ")'s civil branch referred Rochester Drug's non-compliance with the CSA to its Criminal Division, which issued a subpoena for documents and communications to Rochester Drug. Mr. Doud's complaint further alleges that DOJ issue a Grand Jury Subpoena for documents to Rochester Drug on November 1, 2017. Mr. Doud alleges that, after serving as Rochester Drug's CEO of more than 25 years, he was made a scapegoat by other high-level individuals in the company, one of whom told him, in front of the company's Board of Directors, that he would go to prison for his role in Rochester Drug's recent CSA violations. Mr, Doud further alleges that Mr. Brennan, whom his Amended Complaint describes as the Chief Operating Officer and the individual who managed the company's compliance department from June of 2013 to April of 2017, also accused him of being involved in a kick-back scheme or side-deal causing the DOJ's past civil complaint and present criminal investigation.
- 105. Rochester Drug and its current CEO struck back following Mr. Doud's action, filing counter claims against Mr. Doud, alleging, among other things, that he disregarded the company's policies and procedures concerning the sale of controlled substances. Mr. Doud then filed a third party compliant for contribution against Rochester Drug's Board of Directors, alleging that, if Mr. Doud were responsible for failures to comply with the 2015 consent order and/or the criminal investigation, the Rochester Drug Board of Directors is responsible for such

failures, and as he acted with the Board's full knowledge and approval. Mr. Doud further alleged that he acted in the light of regular meetings with the Board, which conducted its own investigation and assessment of matters related to the company's conduct. Mr. Doud further alleged that internal meeting minutes demonstrate that Rochester Drug's Board was involved at every level of, and had knowledge of all aspects of, the company's business.

106. The above violations reflect a pervasive pattern and practice over the last decade of failing to report and stop suspicious orders from which Defendants' operations in New York and the supply of opioids into Albany County would not have been exempt. In addition, these violations of federal law and regulations also constituted violations of New York law.

4. <u>Defendants worked together to sustain their market and boost their profits.</u>

financial relationships with both manufacturers and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion, and which, in the case of Walgreens, CVS, and Rite Aid, were part of the same corporate family. These services often otherwise would not be provided by manufacturers to their downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesale distributors also offer marketing programs, patient services, and other software to assist their dispensing customers.

- 108. The Defendants operating as wholesale distributors had financial incentives from manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill, in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.
- 109. Upon information and belief, each of the Defendants also worked together through trade or other organizations, such as the HDA, the National Association of Chain Drugstores ("NACDS"),³⁴ and the Pain Care Forum ("PCF"), to safeguard the market for opioids and the distribution of opioids.
- 110. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including third party "front groups" who spread deceptive messages about the risks and benefits of opioids. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.
- 111. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national

³⁴ The National Association of Chain Drug Stores is a national trade association that represents traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains with four stores to national companies. Walgreens serves on the Board of Directors of NACDS, as do representatives of Rite Aid and CVS.

response to the ongoing wave of prescription opioid abuse."³⁵ Specifically, PCF members spent over \$740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.³⁶

- 112. Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF. In 2012, membership and participating organizations included major manufacturers as well as the Healthcare Distribution Management Association ("HDMA" (now "HDA")), a trade organization representing Defendants. Upon information and belief, Distributors of prescription opioids actively participated, and continue to participate in the PCF, directly and, at a minimum, through their trade organization.
- 113. Although the entire HDA membership directory is private, the HDA website confirms that Defendants AmerisourceBergen, Cardinal, McKesson, Rochester Drug, and H.D. Smith,³⁷ as well as major manufacturers of prescription opioids were members.
- 114. The closed meetings of the HDA's councils, committees, task forces and working groups provided these Defendants with the opportunity to work closely with each other and with pharmaceutical companies, confidentially, to develop and further their common purpose and interests.
- 115. HDA members were eligible to participate on councils, committees, task forces and working groups, including:

³⁵ Matthew Perrone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, The Ctr. for Pub. Integrity, https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (last updated Dec. 15, 2016, 9:09 AM) (emphasis added).

³⁶ *Id*.

³⁷ H.D. Smith would have been represented by Smith Drug Company, Div. J. M. Smith Corporation.

- a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues;"
- b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members;
- c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members; and
- d. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.³⁸
- 116. HDA also offers a multitude of conferences, including annual business and leadership conferences. HDA advertises these conferences as "bring[ing] together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues." These conferences provided HDA members "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry" and an opportunity to work together.
- 117. Defendants also worked together through joint efforts of the HDA and NACDS.

 The respective CEOs of the HDA and NACDS have spoken with one voice, with respect to

³⁸ <u>Councils and Committees</u>, Healthcare Distribution Alliance, *available at* https://www.healthcaredistribution.org/about/councils-and-committees

³⁹ 2017 <u>Business and Leadership Conference</u>, Healthcare Distribution Alliance, *available at* https://www.healthcaredistribution.org/events/2017-business-and-leadership-conference.

⁴⁰ *Id*.

portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Defendants worked together in other ways as well to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

- 118. As described above, upon information and belief, Defendants also coordinated in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, the HDA—which has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade." This coordination in their lobbying further supports an inference that Defendants worked together in other ways. Further, each Defendant would have known that its own conduct could be reported by others, and thus would have had an incentive to ensure consistency in their dealings with regulatory authorities.
- 119. Taken together, the interaction and length of the relationships between and among the Defendants reflect a deep level of interaction and cooperation between members of the supply chain in a tightly knit industry. Upon information and belief, the Defendants were not operating in isolation but worked together on multiple fronts, to engage in the unlawful sale of prescription opioids.

⁴¹ Matthew Perrone, <u>Pro-Painkiller echo chamber shaped policy amid drug epidemic</u>, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; <u>PAIN CARE FORUM 2012 Meetings Schedule</u>, (last updated Dec. 2011), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

- 120. Upon information and belief, the HDA, NACDS, and the Pain Care Forum are examples of the overlapping relationships and concerted joint efforts to accomplish common goals, and demonstrate that the leaders of Defendants were in communication and cooperation.
- 121. Publications and guidelines issued by the HDA confirm that Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an *amicus* brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.⁴²
- 122. Upon information and belief, Defendants were also a part of a decision-making scheme seeking to control the state and federal government's response to the distribution of prescription opioids and maintain an oversupply of prescription opioids through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.
- 123. Through their participation in the PCF and HDA, Defendants worked to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution.
- 124. As described below, Defendants failed to report suspicious orders and the flow of opioids continued unimpeded.

⁴² See Amicus Curiae Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 5.

5. Defendants ignored red flags of abuse and diversion.

- 125. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database.⁴³ The data necessary to identify with specificity the transactions that were suspicious is in possession of the Defendants, but has not been disclosed to the public.
- 126. Yet, publicly available information confirms that Defendants funneled far more opioids into Albany County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. Upon information and belief, this information, along with the information known only to Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting Albany County.
 - 127. The County's information and belief rests upon the following facts:
- a. Wholesalers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
- b. Wholesalers regularly visit pharmacies to promote and provide their products and services, which allows them to observe red flags of diversion; and
- c. Defendants together may account for more than 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area.
- 128. Upon information and belief, at all relevant times, Defendants were in possession of data or information that allowed them to track prescribing patterns over time. For example, Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help

⁴³ See Madel v. USDOJ, 784 F.3d 448 (8th Cir. 2015).

Defendants identify suspicious orders or customers who were likely to divert prescription opioids.⁴⁴ The "know your customer" questionnaires informed Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

- 129. According to testimony by a Cardinal former Executive Chairman of the Board at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, Cardinal has the ability to request drug dispensing reports, which include all drugs dispensed by a pharmacy, not only those by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale distributors could request similar reports.
- 130. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around Albany County, should have investigated, ceased filling orders for opioids, and reported potential diversion to law enforcement.

⁴⁴ Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at

https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, (available at

https://www.mcguirewoods.com/news-

resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

- 131. Further, Defendants Walgreens, CVS, and Rite Aid, upon information and belief, would have had visibility into the dispensing practices of pharmacies forming part of the same corporate family as these distributors.
- 132. Publicly available data suggests distribution of opioids to Albany County exceeded reasonable medical use and that opioids were likely diverted into Albany County. From 2014-2016, more than 140,000 opioid prescriptions were reported in Albany County, with an estimated population of 309,053. The volume of opioids distributed in Albany County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.
- 133. Further, a prescriber in Albany County was arrested in 2014 for illegal prescribing after an investigation by the DEA uncovered four occasions on which he issued prescriptions from his home or from the parking lot of a gas station without conducting a medical examination or inquiry and without keeping medical records. Upon information and belief, such conduct would have triggered suspicious orders.
- 134. In addition, the crisis of fatal overdoses from prescription opioids in New York communities, including Albany County, has been widely publicized. The County has seen a dramatic rise in opioid-related drug overdose deaths. In contrast to two opioid-related fatalities in 2003, twenty-three people in the County lost their lives to opioid-related overdoses in 2014. Overall, the number of opioid related deaths rose 47% in New York over a five-year period. From 2015 to 1016, the crisis deepened, and the state saw a 29% increase in the number of people who died from opioid-related overdoses. These deaths are attributable to prescription opioids, and increasingly, to illicit opiates, to which people who have become addicted to prescription opioids often transition. The CDC estimates that for every opioid-related death,

there are 733 non-medical users. Moreover, as many as a quarter of the people in the Capital Region personally knew someone who has died of an opioid overdose. Defendants thus had every reason to believe that illegal diversion was occurring in Albany County.

- 135. Upon information and belief, not only were prescription opioids diverted within County, they were being diverted into Albany County. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across jurisdictional boundaries in a variety of ways.
- 136. For example, when authorities in states such as Ohio and Kentucky cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills.

 Residents of other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that these individuals were dubbed "prescription tourists."
- 137. The facts surrounding numerous criminal prosecutions illustrate the common practice. For example, one man from Warren County, Ohio, sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as \$100 a pill—ten times the pharmacy price. In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen individuals involved in the "oxycodone pipeline between Ohio and Florida."⁴⁵ When officers searched the Ohio home of the alleged

⁴⁵ *16 Charged in 'Pill Mill' Pipeline*, Columbus Dispatch (June 7, 2011), http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html.

leader of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone, and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of U.S. District Judge Michael Watson, contributing to a "pipeline of death."

- pill mill; the U.S. attorney's office found that most of the pain clinic's customers came from other states, including North Carolina, Kentucky, Tennessee, Ohio, South Carolina, and Florida. Another investigation in Atlanta led to the 2017 conviction of two pharmacists who dispensed opioids to customers of a pill mill across from the pharmacy; many of those customers were from other states.
- 139. In yet another case, defendants who operated a pill mill in south Florida were tried in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in its decision upholding the venue decision, "[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the [Pain Center of Broward]'s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio, Georgia, and Massachusetts."⁴⁷ The court further noted that

⁴⁶ *Leader of Ohio pill-mill trafficking scheme sentenced*, Star Beacon (July 16, 2015), http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article-5fb058f5-deb8-5963-b936-d71c279ef17c.html.

⁴⁷ United States v. Elliott, 876 F.3d 855, 858 (6th Cir. 2017).

the pill mill "gained massive financial benefits by taking advantage of the demand for oxycodone by Kentucky residents." 48

- 140. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills came from as far away as Arizona and Nebraska.
- 141. Similar pipelines developed in other regions of the country. The I-95 corridor was a significant transport route for prescription pills. The director of the Maine Drug Enforcement Agency has described the oxycodone in Maine was coming up extensively from Florida, Georgia and California. I-95 runs from Miami, Florida, through Maine, including a stretch from New York City to the Connecticut state line.
- 142. Notably, several examples of illegal prescribing and diversion within New York, upon information and belief, would have alerted Defendants to instances of diversion. For example, in 2013, a Long Island internist was indicted on more than 500 felony counts for writing more than \$1 million prescriptions for 5,800 patients at his cash only practice.

 Authorities described the doctor as "a drug dealer in a white coat" who was "dishing [prescriptions] out like candy," and patients explained he was "too busy" conduct examinations and would prescribe anything for \$300.⁴⁹
- 143. In 2015, a Scarsdale doctor and his wife were indicted for allegedly operating a cash-only practice that sold more than 23,600 oxycodone prescriptions, or 3.1 million pills, over

⁴⁸ *Id.* at 861.

⁴⁹ Emily Friedman, *Stopping Dr. Feelgood: The Challenge of Overprescribing* (December 11, 2013), https://www.hhnmag.com/articles/5259-stopping-dr-feelgood-the-challenge-of-overprescribing

a six-year period. According to the DEA, these pills would have been worth \$77 million on the black market.

- 144. More recently, in 2017, multiple prescribers within the State were arrested for illegal practices. From 2015 to 2017, the one doctor has been described as writing more than 8,000 prescriptions for fentanyl and oxycodone. Not only was the doctor described as able to collect \$2 million in fees by charging \$200 \$300 cash for patient visits, an assistant allegedly referred patients to an individual who could buy the prescriptions and resell the drugs on the street. Another New York physician was charged for writing medically unnecessary prescriptions for oxycodone in exchange for goods, money and services over a five-year period. According to a DEA special agent "[i]t is alleged that millions of dollars' worth of pain medication was diverted onto the streets." A New York family physician was also arrested in 2017 for writing more than 14,000 prescriptions (2.2 million pills), most for oxycodone, over a five-year period, charging \$500 in cash for each prescription. And, thirteen people were indicted in New York in a conspiracy involving three Brooklyn medical clinics. According to prosecutors, from 2012 through 2017, the conspiracy put "6.3 million oxycodone pills on New York's black market and generated more than \$24 million for the three clinics."
- 145. Intra- and inter-state transport of diverted pills was not limited to areas described above. For example, according to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.

⁵⁰ Jennifer Barrett, Pharmacy Times, *Physician Charged in Pill Mill Operation* (June 27, 2017), http://www.pharmacytimes.com/news/physician-charged-in-pill-mill-operation.

⁵¹ Eli Rosenberg and Nate Schweber, The New York Times, *Three Brooklyn Clinics*, 6.3 Million Oxycodone Pills and 13 Indictments, (April 17, 2017).

- 146. Along the West Coast, over a million pills were transported from the Lake

 Medical pain clinic in Los Angeles and cooperating pharmacies to the city of Everett,

 Washington. Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to

 Seattle.
- 147. Abundant evidence, thus, establishes that prescription opioids migrated between cities, counties, and states, including into New York. As a result, prescription data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and diversion problem in that specific area. As the criminal prosecutions referenced above show, if prescription opioid pills were hard to get in one area, they migrated from another. Upon information and belief, Defendants would have been fully aware of this phenomenon and profited from it.
- 148. Based upon all of these red flags, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in Albany County.
 - B. <u>Defendants Hid Their Lack of Cooperation with Law Enforcement and Falsely Claimed to be Actively Working to Prevent Diversion.</u>
- 149. When a wholesaler does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action or may not know to take action at all.
- 150. After being caught failing to comply with particular obligations at particular facilities, Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson

claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid \$150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

- More generally, the Defendants publically portrayed themselves as committed to 151. working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."
- 152. Similarly, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Its website offers assurances that the company's Controlled Substances

Monitoring Program ("CSMP") "uses sophisticated algorithms designed to monitor for suspicious orders, and block the shipment of controlled substances." Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

- 153. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients." Another AmerisourceBergen representative has claimed publically, on behalf of the company that, "[a]s a supply chain partner, we are committed to finding comprehensive solutions to mitigate the opioid epidemic impacting our communities, and we understand the important role we play in helping to combat medication diversion and abuse[.]"
- 154. Walgreens, too, publicly portrays itself as committed to working diligently to prevent diversion of these dangerous drugs and curb the opioid epidemic, including through installation of safe-disposal kits at Walgreens pharmacies and plans to make Naloxone available without a prescription, in accordance with state pharmacy regulations. Citing these efforts, Walgreens promotes itself as committed to undertaking "a comprehensive national plan announced earlier this year to address key contributors to the crisis."
- 155. Rite Aid portrays itself as concerned that "[o]pioid addiction and overdose deaths impact every population in the United States from urban areas to rural farm communities and

knows no boundaries racial or economic." It claims to be "committed to working with our patients, local law enforcement, community groups and both federal and state agencies to help reduce the opioid epidemic that is impacting our communities throughout the United States."

- 156. CVS likewise claims to be "playing an active role in the search for solutions to the opioid crisis in a number of ways."
- 157. H.D. Smith, as described above, has denied that its actions contributed to the opioid epidemic under oath in testimony before Congress.
- 158. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, the HDMA (now HDA) and the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:⁵²
 - a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
 - b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."
- 159. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.
- 160. These public statements created the false and misleading impression that the Defendants rigorously carried out their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as

⁵² Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

a matter of corporate responsibility to the communities their business practices would necessarily impact.

- C. <u>By Increasing Opioid Prescriptions and Use and Failing to Maintain</u>

 <u>Effective Controls Against Diversion, Defendants Collectively Fueled the</u>

 <u>Opioid Epidemic and Significantly Harmed the County and its Residents.</u>
- prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use and has served in both sustaining and expanding a market for their opioids. As alleged in the Plaintiffs' Master Form Complaint and Jury Demand in *In re Opioid Litigation*, Index No. 400000 / 2017, incorporated herein by reference, Defendants acted in concert, and conspired with the major manufacturers of prescription opioids to expand and protect the market for prescription opioids.
- 162. Moreover, Defendants compounded the harms from aggressive marketing that overcame barriers to widespread prescribing of opioids for chronic pain by supplying opioids beyond even what this expanded market could bear, and by turning a blind eye to red flags that they were fueling abuse and diversion of these dangerous drugs.
- 163. By continuing to supply and failing to report suspicious orders of opioids,

 Defendants have enabled an oversupply of opioids, which allows non-patients to become

 exposed to opioids, and facilitates access to opioids for both patients who could no longer access

 or afford prescription opioids and addicts struggling with relapse.
- 164. Overall sales of opioids in New York have skyrocketed, and Albany County is no exception. In 2015, health care providers wrote enough opioid prescriptions to medicate every American around the clock for three weeks, and on an average day, more than 650,000 opioid

prescriptions are dispensed in the U.S. From 2014-2016, more than 140,000 opioid prescriptions were reported in Albany County, with an estimated population of 309,053.

- 165. Further, as explained above, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. Roughly 80% of heroin users previously used prescription opioids. A relatively recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into New York communities.
- 166. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants, and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans.
- 167. Opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 183,000 people died in the United States from prescription-related overdoses. According to the New York State County Opioid Quarterly Report Published July, 2017, in Albany County, 31 people died from heroin or other opioids in 2015, and 18 heroin and opioid-related deaths were reported for 2016.
- 168. In Albany County, total opioid deaths from 2010 to 2015 increased by 29 percent.

 More recently, the Albany County Sheriff noted that in the first ten months of 2017 there were

more than 25 heroin-related deaths confirmed plus another 60 suspected. ⁵³ "[I]t's horrifying if you think about it and a lot of people think that it's not going to affect them, it wouldn't happen to us, we're in a beautiful suburban town, it's not going to happen here, but it happens everywhere," said the Sheriff.⁵⁴

- 169. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of Narcan or naloxone—the antidote to opioid overdose. Individuals addicted to opioids are so familiar with the potential for overdose that many choose to use drugs in public places, such as a Walmart bathroom, where they can be found and revived. New York, from 2010 to 2014, saw a 73% jump in the number opioid-related emergency-room visits. In 2014, Naloxone was administered during 12,000 emergency calls, a 57% percent increase from the previous year.
- 170. Opioids have caused injury and illness in Albany County in other respects as well. An increase in Hepatitis C, according to the CDC, is directly tied to intravenous injection of opioids. The opioid epidemic has fueled a rise in hepatitis C in New York. And, notably, a study of a cluster of new hepatitis C cases in one New York area found that participants who had injected prescription opioids were five times more likely to test positive for hepatitis C than study participants who had injected other drugs.
- 171. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses in other respects as well. According to a recent analysis by a Princeton

⁵³ News Channel 13, *New efforts in Albany County to fight heroin epidemic* (October 11, 2017), http://wnyt.com/news/albany-county-opioids-heroin-project-orange-prescription-medication-pills-overdose-death-pharmacy-marras-envelope-voucher/4632277/

⁵⁴ *Id*.

University economist, approximately one out of every three working age men who are not in the

labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014 to 2016, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily. There are also swelling costs from the growing universe of medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by *The Washington Post*, working age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effects medications—essentially, drugs to treat the effects of opioids—generated at least \$4.6 billion in spending nationally in 2015, on top of \$9.57 billion in spending on opioids themselves. In addition, there are also the costs of dispensing opioids—in office visits to obtain refills, count pills, or obtain toxicology screens to monitor potential abuse. The abuse of opioids have caused additional medical conditions that have injured County residents and required care, upon information and belief, often paid for by the County.

172. The deceptive marketing, oversupply, and failure to maintain effective controls to guard against diversion of opioids also had a significant detrimental impact on children. The overprescribing and oversupply of opioids has given young children access to these dangerous drugs, nearly all of which were prescribed for adults in their household. Teenagers too, obtain access to prescription drugs, and suffer addiction and overdose. Young people become addicted to prescription opioids after experimenting with the drugs believing, incorrectly, that prescription drugs are less dangerous than illicit drugs sold on the street. When they do, they too may turn to

heroin and synthetic opioids. Powerful synthetic opioids, such as fentanyl and carfentanil, are so strong that multiple doses of Narcan or naloxone may be required to reverse an overdose. One mother reported that it took six doses to revive her son. Another mother's son survived 13 overdoses.

- been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour. From 2007 to 2009, for every 1,000 hospital discharges in the County, as many as 102 newborns suffered drug related problems.
- 174. Children are also injured by the dislocation caused by opioid abuse and addiction. The County has seen an increase in the number of children entering foster care due to substance abuse as a result of the opioid crisis, a startling trend given that as a whole, the number of New York Children in foster care steadily declined over the past two decades.
- 175. The County provides many services to its residents, and has used these services to combat the opioid epidemic. For example, the Albany County Drug Court works to provide non-

violent substance abusing offenders appropriate, court-supervised treatment and effectively using community resources to improve the opportunity for recovery.

Albany County Opioid Task Force. The Task Force brings together leaders in public health, law enforcement, behavioral health, and the community to work collaboratively toward solutions and help individuals and families affected by opioid addiction and abuse. Among the Task Force's priorities are education, prevention, and public outreach, streamlining access to care, and improving data coordination. "Project Orange," a partnership between the Albany County Department of Health and participating local pharmacies, named after the orange label affixed to controlled substances, provides prepaid envelopes that customers may use to return unused prescription opioids to participating pharmacies. The program aims to provide an opportunity for education about the dangers of extended opioid use and the existence of a black market for prescription opioids — of which many County residents have been and, upon information and belief, remain unaware.

D. <u>Statutes of Limitations are Tolled and Defendants are Estopped From Asserting Statutes of Limitations as Defenses.</u>

1. <u>Continuing Conduct.</u>

- 177. The County contends it continues to suffer harm from the unlawful actions by the Defendants.
- 178. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has

not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment.

- 179. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceived the County and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State and the County that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State and the County, that they are working to curb the opioid epidemic.
- 180. Defendants deliberately and successfully concealed from the medical community, patients, and the County facts sufficient to arouse suspicion of the claims that the County now asserts. The County did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.
- 181. Defendants also fraudulently concealed their misconduct. They have declined to release the detailed data they possess and provide to the DEA regarding the amount and location of their shipments and have worked to keep litigants from obtaining the data from the DEA or making it public. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion and publically portray themselves as committed to fighting the opioid epidemic. However, their public pronouncements are at odds with their concealed misconduct.

182. To the extent that information about Defendants' violations of the federal CSA and its implementing regulations was disclosed through settlement agreements, that information, or many of the Defendants, concerned facilities outside New York. Further, such settlement agreements have typically been followed by or coupled with promises to improve compliance.

E. Facts Pertaining to Claims Under the Racketeer Influenced and Corrupt Organizations Act ("RICO")

- 183. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent." Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, Defendants AmerisourceBergen, Cardinal, and McKesson (the "RICO Supply Chain Defendants") worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.
- 184. As explained above, regulations adopted under the CSA, as well as New York statutes and regulations, require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to maintain a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

⁵⁵ http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response

185. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." New York law is no less stringent.

186. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, Defendants elected to operate in a conspiracy of silence, in violation of the CSA, New York law, and RICO.

any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement

⁵⁶ 21 C.F.R. 1301.74(b).

actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance — intentionally remaining silent to ensure the largest possible financial return.

- 188. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to distribute. In support of this common purpose and fraudulent scheme, the Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.
- 189. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:
- 190. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:
 - a. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

- b. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- c. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and
- d. they did not have the capability to identify suspicious orders of controlled substances or were in the midst of a learning curve.
- 191. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."⁵⁷
- 192. The CSA and the Code of Federal Regulations require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.
- 193. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other documents required to be filed with the DEA.

⁵⁷ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports.

- 194. Upon information and belief, the RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.
- 195. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.
- 196. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which, upon information and belief, number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.
- 197. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by these Defendants or third parties that were foreseeably caused to be sent as a result of these Defendants' illegal scheme, including but not limited to:
 - a. The prescription opioids themselves;

- Documents and communications that supported and/or facilitated requests for higher aggregate production quotas, individual production quotas, and procurement quotas;
- c. Documents and communications that facilitated the purchase and sale of prescription opioids;
- d. RICO Supply Chain Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;
- f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;
- k. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- 1. Deposits of proceeds from the RICO Supply Chain Defendants' distribution of prescription opioids; and
- m. Other documents and things, including electronic communications.
- 198. Each of the RICO Supply Chain Defendants identified shipped, paid for and received payment for the drugs identified above, throughout the United States.
- 199. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State

laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

- 200. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.
- 201. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.
- 202. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.
- 203. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the County that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for prescription opioids from which they could profit.
- 204. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, the County has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include

thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

- 205. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme.
- 206. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.
- 207. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured the County's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.
- 208. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.
- 209. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Albany County, and its residents. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain

profits from unlawful sales of opioids, without regard to the effect such behavior would have on the County and its residents. The RICO Supply Chain Defendants were aware that the County and its residents rely on these Defendants to maintain a closed system of distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

210. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

CAUSES OF ACTION

COUNT I

Deceptive Acts and Practices – New York General Business Law § 349 (Against All Defendants)

- 352. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
 - 353. Defendants' acts were consumer oriented.
- 354. Defendants' acts and/or practices, by acting in concert with manufacturers of prescription opioids, are "deceptive or misleading in a material way" and include but are not limited to:
 - a. misrepresenting the truth about how opioids lead to addiction;
 - b. misrepresenting that opioids improve function;
 - c. misrepresenting that addiction risk can be managed;
- d. misleading doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
 - e. falsely claiming that withdrawal is simply managed;
 - f. misrepresenting that increased doses pose no significant additional risks;

- g. falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment; and
- h. falsely claiming to cooperate with and support efforts to prevent opioid abuse and diversion.
 - 355. Defendants' acts and/or practices caused actual harm to the County.
 - 356. The County has been injured as a result of Defendants' acts and/or practices.
- 357. New York General Business Law § 349 declares unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in the state, and allows any person who has been injured by reason of any violation of that statute to bring an action to recover actual damages.
- 358. Defendants violated New York General Business Law § 349, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.
- 359. Defendants' acts and practices regarding prescribers and consumers as alleged in this Complaint are immoral, unethical, and offensive to established public policy, including:
- a. The policy, reflected in the Albany County 2016-2018 Community Health
 Improvement Plan and Albany County Opioid Task Force, to promote mental health and prevent
 substance abuse, and specifically, to curb the opioid epidemic in Albany County; and
- b. The policy, reflected in N.Y. Comp. Codes R. & Regs. tit. 10 § 80.22, requiring establishment of a system to disclose suspicious orders and reporting of such orders to authorities.
- 360. The County is part of the broad class of persons that may avail themselves of a remedy under § 349.

- 361. The County and its residents have been injured by reason of Defendants' violation of § 349.
- 362. The County is entitled to recover their damages caused by the violation of New York General Business Law § 349 by the Defendants in an amount to be determined at trial, subject to trebling, plus attorneys' fees.

COUNT II False Advertising – New York General Business Law § 350 (Against All Defendants)

- 363. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 364. Defendants violated New York General Business Law § 350, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.
- 365. Defendants' acts were consumer oriented and triggered reliance by patients, physicians and others.
- 366. Defendants' acts and/or practices, in acting in concert with manufacturers of prescription opioids, are "deceptive or misleading in a material way" and include but are not limited to:
 - a. misrepresenting the truth about how opioids lead to addiction;
 - b. misrepresenting that opioids improve function;
 - c. misrepresenting that addiction risk can be managed;
- d. misleading doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
 - e. falsely claiming that withdrawal is simply managed;
 - f. misrepresenting that increased doses pose no significant additional risks;

- g. falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment; and
- h. falsely claiming to cooperate with and support efforts to prevent opioid abuse and diversion.
 - 367. Defendants' acts and/or practices caused actual harm to the County.
 - 368. The County has been injured as a result of Defendants' acts and/or practices.
- 369. The County and its residents have been injured by reason of Defendants' violation of § 350.
- 370. The County is entitled to recover their damages caused by the violation of New York General Business Law § 349 by the Defendants in an amount to be determined at trial, subject to trebling, plus attorneys' fees.

COUNT III PUBLIC NUISANCE (Against All Defendants)

- 371. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 372. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of persons in Albany County by their production, promotion, marketing, and distribution of opioids for use by residents of Albany County.
- 373. Defendants' conduct and subsequent sale of their opioid products is not only unlawful, but has also resulted in substantial and unreasonable interference with the public health.

- 374. Defendants' conduct is not insubstantial or fleeting. Indeed, Defendants' unlawful conduct has so severely impacted public health on every geographic and demographic level that the public nuisance perpetrated by Defendants' conduct is commonly referred to as a "crisis" or an "epidemic." It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.
- 375. Defendants' acts and omissions offend, substantially interfere with, or cause damage to the public in the exercise of rights common to all, in a manner such as to offend public morals or endanger or injure the property, health, safety or comfort of a considerable number of persons.
 - 376. Defendants' conduct is unreasonable and unlawful.
 - 377. Defendants knew of the public health hazard their conduct would create.
- 378. Defendants knew and should have known that their failure maintain effective controls against diversion, including by monitoring, reporting, and exercising due diligence not to fill suspicious orders, would create or assist in the creation or maintenance of a public nuisance.
- 379. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to the County described herein.
- 380. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of disregarding their obligations to maintain effective controls against diversion and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to the County—exactly as would be expected when medical-grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

- 381. Defendants' conduct constitutes a public nuisance.
- 382. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic described in this Complaint.
- 383. Defendants had control over their conduct in Albany County and that conduct has had an adverse effect on rights common to the general public. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, including whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.
- 417. Defendants' conduct directly and proximately caused injury to the County and its residents.
- 418. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Defendants' actions were, at the very least, a substantial factor in the diversion of opioids to illicit secondary channels. Defendants therefore participated to a substantial extent in creating and maintaining the public nuisance. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.
- 419. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to the County.

- 420. The nuisance created, perpetuated, and maintained by Defendants' conduct is abatable.
- 421. The County seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.
- 422. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, the County has taken proactive measures to abate the public nuisance, and the County seeks to expand these efforts.
- 423. The County has suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than New York citizens at large.

 These are harms that can only be suffered by the County.
- 424. The County is asserting its own rights and interests and its claims are not based upon or derivative of the rights of others.
- 425. The County has been injured by reason of Defendants' creation of a public nuisance. The County suffered special injuries distinguishable from those suffered by the general public.
 - 426. Defendants' misconduct alleged in this case is ongoing and persistent.
- 427. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

- 428. In order to abate the public nuisance, the County has incurred expenditures for special programs over and above its ordinary public services.
- 429. The County is entitled to recover its damages caused by Defendants' creation of this public nuisance in an amount to be determined at trial, plus costs and attorneys' fees.

COUNT IV VIOLATION OF NEW YORK SOCIAL SERVICES LAW § 145-B (Against All Defendants)

- 430. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 431. Defendants violated Social Services Law § 145-b, because they knowingly, by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of themselves or others, attempted to obtain or obtained payment from public funds for services or supplies furnished or purportedly furnished pursuant to Chapter 55 of the Social Services Law.
- 432. The County is a "political subdivision" of the State of New York as that term is used in § 145-b (1) (b) and a "local social services district" as that term is used in § 145-b(2).
- 433. As set forth herein, Defendants, upon information and belief, have knowingly set forth false statements or representations, deliberately concealed material facts, and/or perpetuated a fraudulent scheme, in attempts to obtain payment for opioids from public funds for services or supplies furnished by the County pursuant to Chapter 55.
 - 434. By reason of Defendants' violation of § 145-b, the County has been damaged.
- 435. The County is entitled to recover its damages caused by Defendants' violation of § 145-b in an amount to be determined at trial and subject to the apportionment provisions of § 145-b.

COUNT V FRAUD (Against All Defendants)

- 436. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 437. Defendants, individually and acting through their employees and agents, and in concert with each other, knowingly made material misrepresentations and omissions of facts to the County to induce it to purchase, administer, and consume opioids as set forth in detail above.
- 438. In addition and independently, Defendants had a duty not to deceive the County because Defendants had in their possession unique material knowledge that was unknown, and not knowable, to the County, the County's agents, physicians, and the public.
- 439. In each of the circumstances described in, *inter alia*, the foregoing paragraph, Defendants knew that their failure to disclose rendered their prior representations untrue or misleading. Thus, Defendants had a duty not to deceive the County.
- 440. Defendants knew at the time that they made their misrepresentations and omissions that they were false.
- 441. Defendants intended that the County and its residents would rely on their misrepresentations and omissions.
- 442. In the alternate, the Defendants recklessly disregarded the falsity of the representations regarding opioids.
- 443. The County and its residents reasonably relied upon Defendants' misrepresentations and omissions.
- 444. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

- 445. As a result of these representations and/or omissions, the County proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants. As a consequence, these Defendants prevented the County from a more timely and effective response to the opioid crisis.
- 446. By reason of its reliance on Defendants' misrepresentations and omissions of material fact, the County suffered actual pecuniary damage.
 - 447. Defendants' misconduct alleged in this case is ongoing and persistent.
- 448. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.
- 449. The County has incurred expenditures for special programs over and above its ordinary public services.
- 450. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.
- 451. The County is entitled to recover its damages caused by Defendants' fraud in an amount to be determined at trial.

COUNT VI UNJUST ENRICHMENT (Against All Defendants)

452. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

- 453. Defendants acted willfully, wantonly, and with conscious disregard of the rights of the County.
- 454. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the County.
- 455. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the County, including from opioids foreseeably and deliberately diverted within and into Albany County.
- 456. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.
- 457. The County has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.
- 458. These expenditures include the provision of healthcare services and treatment services to people who use opioids.
 - 459. These expenditures have helped sustain Defendants' businesses.
- 460. The County has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.
- 461. The County has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products.
- 462. Defendants, through the wrongful conduct described above, have been unjustly enriched at the expense of the County.

- 463. In equity and good conscience, it would be unjust and inequitable to permit Defendants to enrich themselves at the expense of the County and its residents.
- 464. By reason of the foregoing, Defendants must disgorge its unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the County.

COUNT VII NEGLIGENCE (Against All Defendants)

- 465. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 466. Defendants owed the County a duty, including a preexisting duty, to not expose the County to an unreasonable risk of harm.
 - 467. Defendants have a duty to exercise reasonable care in the distribution of opioids.
- 468. Defendants breached this duty by failing to take any action to prevent or reduce the distribution of the opioids.
- 469. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in distributing and selling dangerous controlled substances.
- 470. The County does not allege that Defendants were negligent only for failure to protect from harm. Rather, Defendants engaged in conduct the foreseeable result of which was to cause harm to the County.
- 471. Defendants have engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the distribution and sale of their prescription opioids.

- 472. Defendants were negligent by distributing and selling opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to the County
- 473. As a proximate result, Defendants and their agents have caused the County to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids. The County has borne the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for its residents and using the County's resources in relation to opioid use and abuse.
- 474. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.
- 475. Defendants were negligent in failing to establish and operate a system to disclose suspicious orders for opioids pursuant to Section 80.22 of the New York Codes, Rules and Regulations.
- 476. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.
- 477. Defendants are in a class of a limited number of parties that can legally distribute opioids, which places them in a position of great trust by the County.
- 478. The trust placed in Defendants by the County through the license to distribute opioids in the County creates a duty on behalf of Defendants to prevent diversion of the medications they supply to illegal purposes.
- 479. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to the County and its residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

- 480. Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.
- 481. Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution and sale.
- 482. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.
- 483. Defendants are in exclusive control of the management of the opioids they distributed in the County.
- 484. The County is without fault and the injuries to the County and its residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the distribution of opioids.
- 485. The County is entitled to recover their damages caused by Defendants' negligence in an amount to be determined at trial.

COUNT VIII

Violation of RICO, 18 U.S.C. § 1961, et seq. – Opioid Supply Chain Enterprise (Against Defendants McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants"))

- 486. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 487. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

- 488. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.
- 489. The RICO Supply Chain Defendants were members of the HDA. Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been for years, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.
- 490. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.
- 491. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a

pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

- 492. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.
- 493. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.
- 494. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

- 495. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).
- 496. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:
 - a. Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
 - b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
 - c. Controlled Substance Violations: The RICO Supply Chain Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.
- 497. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.
- 498. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.
- 499. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily

basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

- 500. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in distributing prescription opioids.
- 501. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding distributing prescription opioids and refusing to report suspicious orders.
- 502. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.
- 503. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured the County's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.
- 504. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants are distinct from the enterprise.
 - 505. The pattern of racketeering activity alleged herein is continuing as of the date of

this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

- 506. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.
- 507. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.
- 508. It was foreseeable to the RICO Supply Chain Defendants that the County would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market causing the opioid epidemic that the CSA intended to prevent.
- 509. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.
- 510. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the County injury in its business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. The County was injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

- 511. The RICO Supply Chain Defendants knew that the opioids they supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.
- 512. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured the County in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.
- 513. Specifically, the County's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:
 - a. Losses caused by the decrease in funding available for the County's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
 - b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
 - c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
 - d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
 - e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
 - f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and

their families;

- g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;
- h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
- i. Costs associated with increased burden on the County's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- k. Loss of tax revenue due to the decreased efficiency and size of the working population in the County;
- l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
- m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.
- 514. The County's injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of the County's injuries. But for the opioid-addiction epidemic created by Defendants' conduct, the County would not have lost money or property.
- 515. The County's injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.
- 516. The County is most directly harmed and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

517. The County seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, and all of the relief sought in this Count as the Court deems just and applicable.

PRAYER FOR RELIEF

WHEREFORE, the County demands judgment against defendants, jointly and severally, as to all Causes of Action, awarding the County in amounts that exceed the jurisdiction of all lower Courts:

- a. A finding that, by the acts alleged herein, Defendants have created a public nuisance;
- b. An injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;
 - c. An order directing Defendants to abate and pay damages for the public nuisance;
- d. Compensatory damages in an amount sufficient to fairly and completely compensate the County for all damages;
 - e. Treble damages, penalties, and costs pursuant to Social Services Law §145-b;
- f. treble damages, penalties and costs pursuant to General Business Law §§349(h) and 350-3(3);
- g. A finding that by the acts alleged herein, the RICO Supply Chain Defendants violated 18 U.S.C. § 1961, et seq.
- h. Actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for the RICO Supply Chain Defendants' violations of 18 U.S.C. § 1961, *et seq*.

- i. Disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;
 - j. Punitive damages;
 - k. Attorneys' fees;
 - 1. Pre- and post-judgment interest, costs and disbursements; and
 - m. Such and further relief as this Court may deem just and proper.

Dated: February 27, 2019

Motley Rice LLC

THE PLAINTIFF, THE COUNTY OF ALBANY BY ITS ATTORNEYS

By:	/s/ Donald A. Migliori	
-----	------------------------	--

Joseph F. Rice (*Pro Hac Vice* to be submitted)
Donald A. Migliori (N.Y. Bar No. 227550)

Lisa M. Saltzburg (*Pro Hac Vice* to be submitted)

MOTLEY RICE LLC

28 Bridgeside Blvd.

Mount Pleasant, South Carolina 29464

Telephone: (843) 216-9000 Facsimile: (843) 216-9450 E-mail: jrice@motleyrice.com E-mail: dmigliori@motleyrice.com E-mail: lsaltzburg@motleyrice.com

Linda Singer (N.Y. Bar No. 2473403)

Elizabeth Smith (*Pro Hac Vice* to be submitted)

MOTLEY RICE LLC

401 9th St. NW, Suite 1001

Washington, D.C. 20004

Telephone: (202) 232-5504 Facsimile: (202) 386-9622

E-mail: lsinger@motleyrice.com E-mail: esmith@motleyrice.com